

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

AVENTIS PHARMA S.A.,  
SANOFI-AVENTIS U.S., LLC

Plaintiffs,

v.

HOSPIRA, INC.

Defendant.

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C.A. No. 07-721-GMS

**PLAINTIFFS' REPLY TO  
COUNTERCLAIMS OF DEFENDANT HOSPIRA, INC.**

Plaintiffs Aventis Pharma S.A. and sanofi-aventis U.S., LLC (collectively, “sanofi-aventis”) for their reply to the Counterclaims of Defendant Hospira, Inc. (“Hospira”), filed on December 10, 2007, hereby state as follows, with the numbered paragraphs corresponding to the like-numbered paragraphs in Hospira’s Counterclaims:

1. Admitted, on information and belief.
2. Admitted.
3. Admitted.
4. Admitted.
5. Admitted.
6. Sanofi-aventis admits that the United States Patent and Trademark Office (“USPTO”) issued U.S. Patent Nos. 5,714,512 (“the ’512 patent”) and 5,750,561 B1 (“the ’561 patent”), naming Rhone-Poulenc Rorer, S.A. as the assignee. Sanofi-aventis also admits that Aventis Pharma S.A. is the owner by assignment of the ’512 and ’561 patents, and that sanofi-aventis has the right, title, and interest in those patents.

7. Admitted.

8. Sanofi-aventis admits that the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act require NDA applicants to disclose to the FDA in their NDA applications “the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.”

9. Admitted.

10. Sanofi-aventis admits, upon information and belief, that Hospira submitted to the FDA a paragraph IV certification in which Hospira alleged that the '512 and '561 patents are invalid, unenforceable, and/or not infringed by its proposed generic product.

11. Admitted.

12. Denied.

### **ANSWER TO COUNT I**

13. Sanofi-aventis reasserts and incorporates by reference its reply to paragraphs 1 through 12 of Hospira's Counterclaims.

14. Admitted.

15. Admitted.

16. Denied.

17. Admitted.

18. Denied.

**ANSWER TO COUNT II**

19. Sanofi-aventis reasserts and incorporates by reference its reply to paragraphs 1 through 18 of Hospira's Counterclaims.

20. Admitted.

21. Admitted.

22. Denied.

23. Admitted.

24. Denied.

**ANSWER TO COUNT III**

25. Sanofi-aventis reasserts and incorporates by reference its reply to paragraphs 1 through 24 of Hospira's Counterclaims.

26. Sanofi-aventis admits, upon information and belief, that Hospira's counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Sanofi-aventis also admits that Hospira seeks a declaration that the claims of the '512 and '561 patents are unenforceable, but denies the remaining allegations of paragraph 26 of Hospira's Counterclaims.

27. Admitted.

28. Denied.

29. Sanofi-aventis admits that there were thirty-five claims pending during prosecution of the '512 patent; that in a rejection dated November 27, 1996, the U.S. Patent & Trademark Office ("USPTO") rejected the thirty-five pending claims over U.S. Patent No. 4,960,790 to Stella *et al.* ("Stella"); and that Stella disclosed certain taxane structures. Sanofi-aventis denies the remaining allegations of paragraph 29 of Hospira's Counterclaims.

30. Sanofi-aventis admits that in response to the rejection over Stella, the '512 patent applicants stated, in addition to several other arguments, that "Stella does not teach or suggest new solutions of Taxol derivatives such as those presently disclosed with less CREMOPHOR® or ethanol." Sanofi-aventis denies the remaining allegations of paragraph 30 of Hospira's Counterclaims.

31. Sanofi-aventis admits that on May 23, 1997, the USPTO issued a notice of allowability, stating that "the prior art does not teach or fairly suggest mixing taxol derivatives in solutions that do not cause anaphylactic shock or alcohol poisoning." Sanofi-aventis denies the remaining allegations of paragraph 31 of Hospira's Counterclaims.

32. Sanofi-aventis admits that the USPTO Examiner indicated that, upon resubmission of an amendment, she would allow the amendment of claims 1 through 23 to recite the limitation "essentially free or free of ethanol," stating that those "[c]laims will read 'free of ethanol.'" Sanofi-aventis denies the remaining allegations of paragraph 32 of Hospira's Counterclaims.

33. Sanofi-aventis admits that, in an amendment dated October 20, 1997, applicants amended claims 1 through 23 to read "essentially free or free of ethanol," and that it did not amend claims 24 through 35 to add this limitation or the limitation "essentially free of alcohol" as alleged in paragraph 33. Sanofi-aventis denies the remaining allegations of paragraph 33 of Hospira's Counterclaims.

34. Sanofi-aventis admits that prosecuting a patent application is typically an *ex parte* process, and that each individual associated with the filing and prosecution of a patent application is subject to the duties found in 37 C.F.R. § 1.56. Sanofi-aventis denies the remaining allegations of paragraph 34 of Hospira's Counterclaims.

35. Denied.

36. Sanofi-aventis admits that none of the claims of the '512 patent, including claims 24 through 35, recite "essentially free or free of alcohol." Sanofi-aventis denies the remaining allegations of paragraph 36 of Hospira's Counterclaims.

37. Denied.

38. Sanofi-aventis admits that, at one time, Rhone-Poulenc Rorer, S.A., was the assignee of both the '512 and '561 patents. Sanofi-aventis denies the remaining allegations of paragraph 38 of Hospira's Counterclaims.

39. Admitted.

40. Sanofi-aventis admits that U.S. Patent Application Serial No. 930,392 was filed August 23, 1993, and issued as U.S. Patent No. 5,403,858. Sanofi-aventis denies the remaining allegations of paragraph 40 of Hospira's Counterclaims.

41. Sanofi-aventis admits that the '512 and the '561 patents both claim priority to the same French Patent Application No. 91/08527, filed on July 8, 1991, and that they were at all times commonly assigned. Sanofi-aventis also admits that the same law firm that prosecuted the '512 patent prosecuted the '561 patent for a portion of its pendency, and that both the '512 and '561 patents generally relate to formulations of taxane derivatives. Sanofi-aventis denies the remaining allegations of paragraph 41.

42. Admitted.

43. Sanofi-aventis admits, that on or about December 20, 1999, the '512 and the '561 patents were assigned to Aventis Pharma S.A. Sanofi-aventis denies the remaining allegations of paragraph 43 of Hospira's Counterclaims.

44. Denied.

45. Sanofi-aventis admits that the '512 and '561 patents had overlapping pendencies at the USPTO, but denies that they were coterminous. Sanofi-aventis denies the remaining allegations of paragraph 45 of Hospira's Counterclaims.

46. Sanofi-aventis admits that one or more individuals employed by Rhone-Poulenc Rhorer, S.A., or Aventis Pharma S.A. was involved in the preparation and/or prosecution of the '072 patent and/or the '582 patent, along with the '512 patent and/or the '561 patent. Sanofi-aventis denies the remaining allegations of paragraph 46 of Hospira's Counterclaims.

47. Sanofi-aventis admits that EP 0522937 and WO 93/00929 were not expressly cited to the Examiner during the prosecution of the '512 patent, but denies that it "failed" to disclose those references, which were not material and/or were cumulative of information already before the Examiner. Sanofi-aventis denies the remaining allegations of paragraph 47 of Hospira's Counterclaims.

48. Sanofi-aventis admits that EP 0522937, WO 93/00928, WO 92/09589, WO 93/16060, WO 93/21173, WO 94/12484, US 5,254,580, and US 5,272,171 were not expressly cited to the Examiner during the prosecution of the '561 patent, but denies that it "failed" to disclose those references, which were not material and/or were cumulative of information already before the Examiner. Sanofi-aventis denies the remaining allegations of paragraph 48 of Hospira's Counterclaims.

49. Denied.

50. Denied.

51. Sanofi-aventis admits that Examiner Amelia Owens was the primary examiner of the '512 patent and Examiner Theodore Criares was the primary examiner of the '561 patent. Sanofi-aventis denies the remaining allegations of paragraph 51 of Hospira's Counterclaims.

52. Denied.

53. Denied.

54. Admitted.

55. Denied.

56. Sanofi-aventis states that Hospira's prayer for relief does not require a response, but sanofi-aventis denies that Hospira is entitled to any of the relief it seeks.

57. Sanofi-aventis denies each and every allegation of Hospira's Counterclaims not heretofore admitted or denied and further denies that Hospira is entitled to any relief whatsoever from sanofi-aventis on the basis of any of the purported claims for relief contained in Hospira's Answer, Affirmative Defenses, and Counterclaims.

#### **PRAYER FOR RELIEF**

WHEREFORE, sanofi-aventis respectfully requests that this Court enter judgment in its favor and against Hospira as follows:

- (1) dismissing Hospira's Counterclaims with prejudice;
- (2) granting sanofi-aventis the relief it requests in its Complaint;
- (3) awarding sanofi-aventis its costs and expenses in this action; and
- (4) awarding sanofi-aventis any further and additional relief as this Court deems just and proper.

ASHBY & GEDDES

*/s/ Tiffany Geyer Lydon*

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